

## EU Declaration of Conformity for Class I\_I\_Bissgabel Set\_76063989


Document Information (OTCS)	
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Signatures	
Author(s)	The signatures of all involved signatories are added on the last page of this document.
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## EU Declaration of Conformity according to Medical Device Regulation MDR 2017/745 Annex IV

We hereby declare that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the below mentioned products meet the provisions of the EU Regulation above. All supporting documentation is retained on the premises of the manufacturer and the Notified Body.

<b>Products</b>	<b>Bite Fork Bite Fork Set</b>
<b>Basic-UDI-DI</b>	763081341XBITE002VW

<b>Legal manufacturer</b>		
	Candulor AG Boulevard Lilienthal 8 8152 Glattpark/Schweiz www.candulor.com	Phone: +41 (0) 78 694 3311 www.candulor.com Legal Form: Joint Stock Corporation Corporate Headquarters: 8152 Glattpark Registration No.: CHE-107.821.754 VAT No.: CHE-107.821.754

<b>EU Declaration of Conformity Information</b>	
<b>EC-REP</b>	SRN: DE-AR-000005472 Candulor Dental GmbH Am Riederngraben 6 78238 Rielasingen-Worblingen Germany
<b>SRN (Legal Manufacturer)</b>	CH-MF-000015795
<b>Intended Purpose</b>	Bite registration
<b>Regulations and Directives</b>	<b>2017/745</b> Medical Device Regulation
<b>EU Classification</b>	<input checked="" type="checkbox"/> Medical Device
<b>EU Risk Class (MDR Annex VIII)</b>	Class I 
<b>Conformity Assessment Procedure (MDR Annex IX)</b>	Quality Management System
<b>EC Certificate No.</b>	G20 090341 0017 Rev. 00
<b>Valid until</b>	2028-11-01

**Attachment to EU Declaration of Conformity**

Article No.	Description	MDR Classification (EU)	Rule MDR (EU)
000662451	Bissgabel	I	5
000662453	Bissgabel Set	I	5

Revision History			
Version	Date	Author	Remark
1.0	2021-05-20	Miriam Stange	First MDR Version
2.0	2021-12-02	Miriam Stange	Correction of validity date
3.0	2024-05-16	Miriam Stange	Removal of Basic UDI-DI HIBC / use of Basic UDI-DI GS1; Removal of DE SRN: Correction of validity date
4.0	2025-05-23	Alexander Schwaszta	1 <sup>st</sup> . MDR PMS and new template

## Signing Page

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Date: Monday, 26 May 2025, 13:03 W. Europe Daylight Time  
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